

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The efficacy and safety of cinnarizine and sodium valproate in prophylaxis of migraine among children and adolescents aged 6 to 17: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

We aim to investigate the efficacy and safety of cinnarizine and sodium valproate in pediatric migraine prevention and comparing to placebo

Design

Pragmatic, community based, parallel group, double blind, randomised controlled trial

Settings and conduct

Prospective clinical trial in Childrens' Medical Center, Tehran University of Medical Sciences, Tehran, Iran. All investigators, patients, and their parents are masked during the study.

Participants/Inclusion and exclusion criteria

Patients aged 6 to 17 years old with migraine (with or without aura), diagnosed according to the IHS criteria can be included. They have to have four or more migraine attack per 4 weeks; or severe dysfunction in daily activity. Headaches must not relate to any known structural brain lesion or other systemic conditions. Patients with chronic headache, complications of migraine or other migraine variants will be excluded. Focal neurologic deficit, history of diagnosed sensitivity to cinnarizine and sodium valproate, as well as pregnancy are other exclusion criteria. Patients who took prophylactic therapy for migraine within 8 weeks before study could not include into the study.

Intervention groups

Three arms in the study are 1) individuals receiving cinnarizine; 2) patients who will be under treatment with sodium valproate; and 3) participants getting placebo

Main outcome variables

Headache frequency; Headache intensity; More than 50% responder rate; Adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201206306907N4**
Registration date: **2012-09-15, 1391/06/25**
Registration timing: **prospective**

Last update: **2019-03-21, 1398/01/01**

Update count: **1**

Registration date

2012-09-15, 1391/06/25

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2011-12-27, 1390/10/06

Actual recruitment start date

2015-02-18, 1393/11/29

Actual recruitment end date

2017-11-17, 1396/08/26

Trial completion date

2018-03-11, 1396/12/20

Scientific title

The efficacy and safety of cinnarizine and sodium valproate in prophylaxis of migraine among children and adolescents aged 6 to 17: a randomized, double-blind, placebo-controlled clinical trial

Public title

Cinnarizine and sodium valproate in prophylaxis of pediatric migraine .

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with migraine (with or without aura), diagnosed according to the International Headache society criteria Patients who had at least four migraine attacks per 4 weeks; or sever dysfunction in daily and school activities during prospective baseline phase.

Exclusion criteria:

Chronic headache, complications of migraine or other migraine variant Children and adolescents with Focal neurologic deficit History of diagnosed sensitivity to each of drugs that used in the study Patients who took prophylactic therapy for migraine within 8 weeks before study. Headaches related to structural brain lesions Pregnancy

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **109**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible outpatients were randomly assigned in a 1:1:1 ratio by permuted block randomization (block sizes of four) via an interactive web response system to receive either cinnarizine, sodium valproate or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study medications were coded and administered by a nurse of our medical center who was not informed about the clinical characteristics of cases. Investigators, participants, and their parents were masked during the course of the study until the code was broken at the end of the trial. Cinnarizine, sodium valproate, and placebo were provided as identical tablets in similar shapes and sizes in neutral containers.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

tehran university of medical science

Street address

16 azar avenue,medical ethics committee

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2009-09-23, 1388/07/01

Ethics committee reference number

35461

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

frequency of headache

Timepoint

frequency of frequency of each attack in a month

Method of measurement

questionnaire

2**Description**

intensity of headache

Timepoint

intensity of each attack

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

1

Description

adverse effects

Timepoint

in the double-blind phase of the study

Method of measurement

ask from participants and parents

2

Description

More than 50% responder rate

Timepoint

in the double-blind phase of the study and baseline

Method of measurement

ask from participants and parents

Intervention groups

1

Description

We randomly divided participants in 3 groups: cinnarizine group received one Cinnarizine tablet (37.5 mg for patients aged 6 to 11 and 50 mg for others aged 12 to 17) per day. All drugs had a same color, package, and shape. Patients could use analgesics for abortive treatment of acute migraine attacks during the study. At 4th, 8th and 12th weeks of the second phase of the study, follow up visits were done. Participants' diaries were checked and with detailed questionnaires, any medicine-related side effects were investigated.

Category

Prevention

2

Description

We randomly divided participants in 3 groups: sodium valproate group received 10-20 mg/kg/day of sodium valproate. All drugs had a same color, package, and shape. Patients could use analgesics for abortive treatment of acute migraine attacks during the study. At 4th, 8th and 12th weeks of the second phase of the study, follow up visits were done. Participants' diaries were checked and with detailed questionnaires, any medicine-related side effects were investigated.

Category

Prevention

3

Description

Control group: We randomly divided participants in 3 groups: placebo group received tablets similar to cinnarizine and sodium valproate groups in color, package, and shape. Patients could use analgesics for abortive treatment of acute migraine attacks during the study. At 4th, 8th and 12th weeks of the second phase of the study, follow up visits were done. Participants' diaries were checked and with detailed questionnaires, any medicine-related side effects were investigated.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic Of Children Medical Center Hospital of Tehran
University of Medical Sciences(markaz tebibi)

Full name of responsible person

Dr Mahmoodreza Ashrafi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research Center of clinic Of Children Medical Center
Hospital of Tehran University of Medical Scienc

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Gharib avenue, Clinic Of Children Medical Center
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Mahtab Ramezani
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected data about primary and secondary outcomes

When the data will become available and for how long

After publication of paper

To whom data/document is available

To people working in academic institutions

Under which criteria data/document could be used

Data can be used if the authors' names were mentioned

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

After receiving the request we will consult to all authors and the data can be share in a week

Comments